UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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SAMUEL COLESON, JR.,

Plaintiff,

- against -

QUALITEST PHARMACEUTICAL MANUFACTURE, ET AL.,

Defendants.

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17-cv-5381 (JGK)

MEMORANDUM OPINION AND ORDER

JOHN G. KOELTL, District Judge:

The plaintiff, Samuel Coleson, Jr., proceeding pro se, brings this action against Teva Pharmaceutical, Inc. ("Teva") and Vintage Pharmaceuticals, LLC ("Vintage"),[1] two manufacturers of risperidone, a generic equivalent of the antipsychotic Risperdal, based on injuries suffered by the plaintiff after taking risperidone. Risperidone (and Risperdal) is an antipsychotic prescription drug used to treat schizophrenia and bipolar mania. The plaintiff alleges that he suffered injuries because the defendants failed properly to warn on the drug's label of risperidone's side effects on male patients and because

[1] The Complaint misidentifies Vintage as "Qualitest Pharmaceutical Manufacture," a "subsidiary of Endo Pharmaceuticals," as well as "Par Medical." Am. Compl. (Dkt. No. 23). The defendants advise in their responsive papers that the proper name of the defendant Qualitest is now Vintage Pharmaceuticals, LLC.

the drug suffers from a design defect. The plaintiff filed his Complaint on July 14, 2017 and amended the Complaint on November 13, 2017 (the "Amended Complaint"). The defendants now move to dismiss all of the plaintiff's claims pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

I.

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the allegations in the complaint are accepted as true, and all reasonable inferences must be drawn in the plaintiff's favor. McCarthy v. Dun & Bradstreet Corp., 482 F.3d 184, 191 (2d Cir. 2007). The Court's function on a motion to dismiss is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." Goldman v. Belden, 754 F.2d 1059, 1067 (2d Cir. 1985). The Court should not dismiss the complaint if the plaintiff has stated "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). While the Court should construe the factual allegations in the light most favorable to the plaintiff, "the tenet that a

court must accept as true all of the allegations contained in the complaint is inapplicable to legal conclusions." Id.

When faced with a pro se complaint, the Court must "construe [the] complaint liberally and interpret it to raise the strongest arguments that it suggests." Chavis v. Chappius, 618 F.3d 162, 170 (2d Cir. 2010) (citation and internal quotation marks omitted). "Even in a pro se case, however . . . threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. (citation omitted). Thus, although the Court is "obligated to draw the most favorable inferences" that the complaint supports, it "cannot invent factual allegations that [the plaintiff] has not pled." Id.

When presented with a motion to dismiss pursuant to Rule 12(b)(6), the Court may consider documents that are referenced in the complaint, documents that the plaintiff relied on in bringing suit and that are either in the plaintiff's possession or that the plaintiff knew of when bringing suit, or matters of which judicial notice may be taken. See Taylor v. Vt. Dep't of Educ., 313 F.3d 768, 776 (2d Cir. 2002).

**II.**

Risperidone is the generic version of Risperdal, an antipsychotic prescription drug used to treat schizophrenia and

bipolar mania in adult patients. Am. Compl. 5. The brand-name drug, Risperdal, is manufactured by Johnson & Johnson and its subsidiary Janssen Pharmaceuticals, Inc. ("Janssen"). Coleson v. Janssen Pharm., Inc., 251 F. Supp. 3d 716, 718 (S.D.N.Y. 2017) ("Coleson I"). The plaintiff originally sued Johnson & Johnson and Janssen, also on the basis of failure to warn and design defect. See Coleson I, 251 F. Supp. 3d at 718. That case was dismissed when it was determined that the manufacturer of a name-brand drug (Risperdal) is not liable for any failure to warn or design defects associated with the drug's generic equivalents and because the plaintiff could not show that he ever took Risperdal. Coleson I, 251 F. Supp. 3d 721, 722. Teva and Vintage, the defendants in this case, are two of the manufacturers that the U.S. Food and Drug Administration (the "FDA") authorizes to produce risperidone.[2]

The FDA first approved Risperdal in 1993. Id. at 718. Since at least 1996, Risperdal's FDA-approved disclosures have indicated that Risperdal is associated with endocrine-related side effects, including gynecomastia, the non-cancerous

[2] The FDA approved Teva's abbreviated new drug application ("ANDA") to manufacture risperidone on Jun 30, 2008. See https://www.accessdata.fda.gov/SCRIPTS/CDER/OB/RESULTS_PRODUCT.CFM?APPL_TYPE=A&APPL_NO=076228. The FDA approved Vintage's ANDA to manufacture risperidone on December 3, 2010. See https://www.accessdata.fda.gov/SCRIPTS/CDER/OB/RESULTS_PRODUCT.CFM?APPL_TYPE=A&APPL_NO=079158.

enlargement of male breasts, and galactorrhea, the production of breast milk independent of childbirth. Id. Accordingly, the January 7, 2009 label of risperidone lists hyperprolactinemia in its "Warnings and Precautions" section, stating:

> As with other drugs that antagonize dopamine $D_2$ receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. . . . "

Vintage Mem. Law Supp. Mot. Dismiss Ex. A.

The plaintiff was first prescribed risperidone in or around July 2010, after being diagnosed with schizophrenia mania and bipolar disorder at the Woodhull Hospital. See Compl. 3; Coleson I, 251 F. Supp. 3d. at 718. The plaintiff continued taking risperidone through late 2013 or early 2014, when he switched to a different antipsychotic medication, Seroquel, which is also linked to gynecomastia. Coleson I, 251 F. Supp. 3d at 719. Around the same time, the plaintiff consulted his doctors about chest pain, the development of a lopsided chest, and discharge from his chest. Id. The plaintiff's doctor, Dr. Ajay Shah, examined the plaintiff on May 30, 2014 and determined that the plaintiff did not have gynecomastia. Id. On September 26, 2014,

Dr. Shah confirmed that that the plaintiff did not have gynecomastia. Id. In or around March 2015, the plaintiff was diagnosed with gynecomastia. Id.; see also Am. Compl. 1. The plaintiff subsequently underwent a bilateral mastectomy. Compl. 2; Am. Compl. 1. The surgery left the plaintiff with scars from his armpits to the center of his chest. Am. Compl. 1. The surgery also caused the plaintiff significant pain and suffering. Am. Compl. 2.

**III.**

The defendants move to dismiss the plaintiff's claims on the ground that they are preempted by federal law. The defendants contend that they are required by federal law to ensure that both the label and design of risperidone are the same as those for Risperdal, the brand-name drug approved by the FDA. Thus, the defendants argue, any state law products liability claims that would have required them to change either the labeling or composition of risperidone -- such as the plaintiff's failure to warn and design defect claims -- are preempted. The defendants are correct.

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl.2. "[S]tate law is naturally preempted to

the extent of any conflict with a federal statute." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000) (footnote omitted). That is, preemption exists "where it is impossible for a private party to comply with both state and federal law . . . ." Id. (citations omitted).

Under the Supreme Court's decisions in PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011) and Mut. Pharm. Co. v. Bartlett, 570 U.S. 472 (2013), state law products liability claims against the manufacturers of generic drugs based on failure to warn and design defect are preempted by the provisions of federal law that require the labeling and composition of generic drugs to be identical to those of their name-brand counterparts. That is because under the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, also known as the Hatch-Waxman Act, a generic drug's approval by the FDA -- which approval is required under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. -- is conditioned on the generic drug being "identical to the already-approved name-brand drug in several key respects," namely:

> the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same "active ingredient" or "active ingredients," "route of administration," "dosage form," and "strength" as its brand-name counterpart. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Second, a proposed generic must be "bioequivalent" to an approved brand-name drug. § 55(j)(2)(A)(iv). That is, it must have the same "rate and extent of absorption" as the brand-name drug.

> § 355(j)(8)(B). Third, the generic drug manufacturer must show that "the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug." § 355(j)(2)(A)(v).

Bartlett, 570 U.S. at 477.

This "duty of 'sameness'" extends beyond the approval process for a generic drug. Mensing, 564 U.S. at 613. In Mensing, the Supreme Court accepted the FDA's interpretation that the label and composition of a generic drug must always be the same as its name-brand equivalent. Id. Thus, the defendants could not have altered risperidone's label to strengthen its warnings about gynecomastia, nor fiddle with its composition to mitigate that possible side effect, without violating federal law. However, just as with the claims at issue in Mensing and Bartlett, the plaintiff's failure to warn and design defect claims in this action would have required the defendants to do just that.[3] Thus, just as in those cases, the plaintiff's claims are preempted.

The defendants' motions to dismiss the plaintiff's claims for failure to warn and design defect are therefore **granted.**

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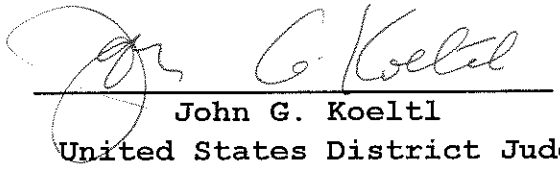
[3] In Bartlett, the Supreme Court rejected the argument that a generic drug manufacturer could avoid liability for state law products liability claims by ceasing to sell a generic drug in particular states. See Bartlett, 570 U.S. at 475.

## CONCLUSION

The Court has considered all the parties' arguments. To the extent any arguments are not specifically addressed above, they are either moot or without merit. The defendants' motion to dismiss the Amended Complaint is **granted** and the case is **dismissed with prejudice.** The Clerk of Court is directed to close all pending motions.

**SO ORDERED.**

**Dated:** **New York, New York**
**May 4, 2018**



**John G. Koeltl**
**United States District Judge**